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FOOD SAFETY AND QUALITY

USDA Improves Inspection Program for Canadian Meat, but Some Concerns Remain

GAO

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Resources, Community, and
Economic Development Division

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The Honorable Max S. Baucus
The Honorable Thomas A. Daschle
United States Senate

The Honorable Byron L. Dorgan
The Honorable Pat Williams
House of Representatives

The Federal Meat Inspection Act requires that meat products imported into the United States be produced under inspection systems that are at least equivalent to the United States system and that the products are wholesome, unadulterated, and properly marked, labeled, and packaged. The U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) is responsible for determining that foreign inspection systems are equivalent to that of the United States and for inspecting imported meat products at the port of entry to help ensure their integrity.[1]

Concerned about FSIS' procedures and practices for ensuring the wholesomeness of imported Canadian meat, you asked us to (1) review USDA's efforts to document that Canada's meat inspection system is equivalent to that of the United States, (2) analyze inspection and rejection data for U.S. and Canadian meat crossing the border, and (3) suggest alternative measures to strengthen USDA's import inspection procedures for Canadian meat.

Background

USDA's reinspection of meat imported from Canada is a quality check designed to ensure that Canada maintains its equivalent inspection system. The primary assurance that Canadian meat complies with U.S. standards is an FSIS determination that the Canadian meat inspection system is "at least equal to" the U.S. inspection system. FSIS interprets this "equivalency" standard as meaning that controls and practices in a foreign country do not have to be identical to those in the United States if they achieve the same results. FSIS reviews and determines the equivalency of a foreign country's inspection system using risk analysis. Use of this approach resulted from FSIS' recognition of the need to evaluate a country's overall inspection system rather than examining individual foreign plants, which

[1]FSIS often refers to import inspections as reinspections to recognize that the exporting country's inspectors have already inspected and approved the meat.

had been FSIS' practice. (Apps. I and II discuss in more detail FSIS' approach to determining equivalency.)

In January 1989, FSIS changed its inspection program for Canadian meat[2] to make it easier for the meat to enter the United States. This action was in response to provisions to minimize inspections and remove barriers to trade in the 1988 United States-Canada Free Trade Agreement. The changes, which FSIS called streamlined procedures, eliminated some inspections and reduced others. Key elements of streamlined inspection included (1) giving the Canadian plants advance notice when FSIS selected a shipment for inspection and (2) having Canadian government inspectors draw the samples. Shipments not selected for inspection could proceed directly to their delivery point.

In previous reports,[3] we noted that documentation by FSIS was inadequate to support its determination that the Canadian meat inspection system is at least equivalent to the U.S. system. We also raised several concerns regarding the streamlined procedures, including the advance notice and the use of Canadian inspectors to draw the samples. We concluded that, as designed, the procedures could continue to be a source of allegations, controversy, and criticism and might erode consumer confidence in the inspection system. On July 14, 1992, USDA announced plans to discontinue streamlined inspection and implement alternative measures.

Results in Brief

In March 1992, FSIS reported that it had carried out an in-depth study that confirmed that the Canadian meat inspection system was equivalent to the U.S. system.[4] The documentation supporting the study provides evidence of a detailed, organized risk analysis of the Canadian system—the same process FSIS uses to determine the eligibility of other foreign countries that export meat to the United States. However, the study relied on the judgments of FSIS' professional staff about the scientific and public health implications of differences between the two countries' systems, without any outside assessment of the validity of their judgments. Furthermore, although the study analyzed the Canadian system's control over risks in 50

[2]Although the United States has separate legislation covering meat and poultry, references in this report to meat include poultry unless otherwise noted.

[3]Food Safety: Issues USDA Should Address Before Ending Canadian Meat Inspections (GAO/RCED-90-176, July 6, 1990) and Food Safety and Quality: Inspection of Canadian Meat Imports Under USDA's Streamlined Procedures (GAO/T-RCED-92-18, Oct. 31, 1991).

[4]Equivalency Study of the United States and Canadian Meat and Poultry Inspection Systems: Summary Report (International Programs, Food Safety and Inspection Service, Mar. 1992).

critical inspection areas, we found that the study did not assess the system's control of or testing for drugs approved for use in Canada but not approved for use in the United States.

Our current review found no significant change in inspection and rejection data on Canadian meat entering the United States since our October 1991 testimony, when we reported that inspection rates were generally constant. Rejection rates (by weight) dropped from 6 percent to less than 3 percent from 1989 to 1991. However, inspection data on U.S. meat entering Canada, provided to us by Agriculture Canada (USDA's counterpart) in March 1992, show that Canada inspects almost one-half of U.S. imports—a rate over twice the U.S. rate for inspecting Canadian meat. FSIS officials were unaware of the higher Canadian inspection rate until we brought it to their attention. As shown in appendix IV, the rejection rate (by weight) for U.S. meat inspected by Canada fluctuated between 3 percent and 6.5 percent from 1989 to 1991.

We identified several measures that FSIS could consider to strengthen FSIS' reinspection program for meat traded between the two countries while still meeting the provisions of the Free Trade Agreement. On July 14, 1992, following a conference on our findings with USDA in which we discussed the disparate inspection rate and differences in the streamlined program associated with it, USDA and Agriculture Canada announced plans to replace the streamlined inspection procedures. In their place, FSIS plans to adopt the measures we had identified, including having FSIS inspectors control sample selection and harmonizing U.S. and Canadian sampling criteria and methodology to achieve comparable inspection rates. In making these changes, FSIS is addressing many of the inherent program weaknesses that have contributed to the controversy surrounding the program.

Equivalency Study's Documentation Provides Current, Specific Information, but Some Concerns Remain

In July 1990, we reported that FSIS' equivalency determination was outdated and not sufficiently documented to allow an independent, objective review of how FSIS arrived at this determination. FSIS responded by updating its determination and, in March 1992, released a summary report concluding again that the Canadian inspection system is equivalent to the U.S. inspection system.

In the summary report and related documentation, FSIS has addressed the concerns we raised in 1990. That is, FSIS has developed current and specific background information to allow review of its process for

determining equivalency. The documentation provides evidence of a detailed, organized risk analysis of the Canadian inspection system—the same process FSIS uses to determine the eligibility of any foreign country exporting meat to the United States. FSIS assessed risk by focusing on 50 critical review points in five risk areas: contamination, disease, economic fraud/compliance, processing, and residues. FSIS' summary report includes a brief comparison of the two countries' systems on each of the critical review points and is supported with documentation that includes laws, regulations, and guidance material governing Canada's meat inspection system.

In addition to reviewing the overall equivalency process and supporting documentation, we also reviewed the two countries' (1) detection and control of the bacteria Listeria monocytogenes, (2) use and monitoring of animal drugs, and (3) lists of foreign countries approved to export meat products. Various differences exist in all three areas, but we found no instances that FSIS considered to have a significant impact on equivalency (see app. III). However, in reviewing FSIS' assessment of Canada's listeria control program, we found that evaluating the significance of differences between the United States' and other countries' inspection systems can require FSIS professional staff to make difficult scientific and public health judgments. Also, we had concerns about (1) the absence of an outside assessment of the equivalency process and the related judgments by FSIS staff and (2) the lack of a review of Canada's control and testing of drugs approved in Canada but not in the United States.

FSIS' Assessment of Inspection System Differences Involves Difficult Judgments

While FSIS' study determined that the Canadian inspection system is equivalent to the U.S. system, differences do exist. Whether these differences are significant enough to affect equivalency can be difficult to determine, and the ultimate determinations are not easily validated. FSIS relies on the professional judgment of its expert staff to make these determinations. For example, in its response to a 1989 USDA Inspector General's report,[5] which criticized FSIS efforts to ensure that foreign countries met U.S. residue standards, FSIS stated:

> Our standard of acceptability is equivalence with the U.S. inspection system; this means that controls and practices do not have to be identical to those in the United States if they achieve the same results. Residue control is a dynamic field, both in the United States and in other countries. Applicability of the principle of equivalence in this complex area

[5]Food Safety and Inspection Service Follow-up Audit of the Imported Meat Process (USDA/OIG Audit Report No. 38002-4-Hy, Mar. 1989).

requires continuous careful judgment . . . . Our method of review is to use technical experts familiar with the U.S. system and trained in the disciplines which support that system. We rely on their professional expertise and apply scientific principles in the legal and trade policy context in which we operate.

Our review of FSIS' assessment of differences in U.S. and Canadian procedures to control listeria showed that the two countries use entirely different approaches for detecting listeria. (The United States relies on end-product testing for listeria, while Canada relies on testing the environment, i.e., workers and work areas, in which the food is processed.) Although they initially decided that Canada's procedures were unacceptable, FSIS officials, after further study, later decided that Canada's procedures did not present problems. Nevertheless, officials from both countries told us that they are discussing harmonizing their procedures because they recognize that the differences perpetuate criticism and debate over whether a "best" method for detection and control of listeria exists, and what that method might be.

Equivalency Study Did Not Analyze Differences in Animal Drug Approvals

Under the Federal Meat Inspection Act, meat containing residues of drugs not approved for use on food-producing animals in the United States cannot be imported. Pursuant to the act, the Secretary of Agriculture annually certifies that Canada and other foreign countries have programs to ensure compliance with U.S. residue standards. Therefore, knowledge of differences in Canadian drug approval/usage is important in determining the equivalency of the Canadian residue program. The Assistant Deputy Administrator for the FSIS International Programs office explained, however, that identifying differences between countries in what drugs have been approved is very difficult. For example, he noted that drug manufacturers often market the same drug to different countries under different names. As a result, FSIS officials must also make judgments in determining whether a foreign country's system complies with U.S. drug residue standards.

FSIS officials told us that, consistent with the systems approach to risk analysis, the focus in the residue risk area was on making sure that Canada had a reasonable system for approving animal drugs and monitoring for drug residues. In their view, the equivalency documentation shows that Agriculture Canada has such a system. Therefore, FSIS did not assess the adequacy of Canadian controls or testing for individual drugs approved for use on food-producing animals in Canada but not in the United States.

However, as pointed out in the previously cited 1989 USDA Office of Inspector General audit report, four of five foreign countries covered in the report (Canada was one of the four) received residue certification from USDA even though they allowed the use of animal drugs not approved in the United States but did not include these drugs in their residue test plans. As a result, the Inspector General recommended that FSIS ensure that foreign countries' residue testing plans address drugs that are not approved for use in the United States.

Although FSIS responded positively to the recommendation, it has not fully implemented it for Canada. In a March 1989 letter, the FSIS Administrator advised the Inspector General that as a first step in evaluating foreign residue testing plans, FSIS had begun documenting and evaluating drug use in countries certified to export meat products to the United States. The Administrator explained, however, that such analysis was not simple or clear-cut and estimated that the project, which began in July 1987, would take 5 years to complete. When we evaluated the equivalency review documentation, FSIS did not have complete information on animal drugs approved in Canada that are not approved in the United States. In fact, the most current FSIS listing of Canadian animal drugs was 4 years old.

Although we did not attempt to accomplish an all-inclusive analysis, we identified seven drugs approved for use on food-producing animals in Canada that are not approved for use in the United States. Canada's 1992 residue testing plan indicates coverage of six of the seven drugs we identified, including three for which the United States had previously withdrawn approval after they were identified as possible carcinogens.

Furthermore, because of the way in which the United States tests meat imports, animal drugs used in Canada may not be tested for during reinspection. The U.S. import residue testing program is not based on independent judgments about the risk of particular residues from foreign countries. Instead, it is essentially driven by the domestic residue testing program. Residue testing in the import program mirrors, though on a smaller scale, the priorities of the domestic analysis program. However, this testing may not include drugs used in foreign countries, including Canada.

In our discussions with Agriculture Canada officials, they said that the issue of differences in animal drug approvals between the United States and Canada should be put in the proper perspective. They pointed out that while a few drugs are approved in Canada but not in the United States, the

converse is also true. They said that quite a few drugs used in the United States are not licensed for use in Canada.

Peer Review Could Add Credibility to FSIS' Equivalency Review Process

While FSIS management reviewed the equivalency study, there was no review by scientists and public health experts outside of USDA. Although there is no legal or regulatory requirement that outside experts review FSIS' equivalency studies, such a peer review could be valuable because equivalency is a difficult concept to define and, at times, a subjective process. A one-time, independent assessment and corroboration of FSIS' implementation of the equivalency process could add credibility to the Canadian study and to future equivalency studies of other countries. (About 40 other countries are being studied for equivalency using the same process followed for Canada.)[6]

The issue of how equivalency should be defined has resulted in considerable controversy in other contexts over what kinds of differences will be tolerated between countries' inspection systems. For example, while USDA's traditional criterion is that foreign inspection systems should be "at least equal to" that of the United States, a provision of the 1985 Farm Bill amended the Poultry Products Inspection Act to require that imported poultry products meet standards that are "the same as" those for U.S. products. While USDA interpreted "the same as" to mean "at least equal to," this interpretation was struck down by the U.S. District Court for the Southern District of Mississippi in April 1992. USDA has appealed this decision.

A peer review of FSIS' equivalency process, including the agency's approach to weighing the significance of inspection system differences, could help dispel future challenges to FSIS' decisions in this area. The current environment in international trade is beset with controversies and concerns over the safety of imported food, as exemplified by the ban imposed by the European Community on imported beef from cattle raised using growth hormones and by suggestions that the high rejection rate of imported Canadian meat in 1989 (discussed in our 1991 testimony) indicated that the Canadian inspection system may not be equivalent to the U.S. system. As long as there are differences between countries' inspection systems, the potential exists for a food safety problem to expand beyond an individual incident to implicate a country's entire industry as well as shake consumer confidence in the effectiveness of U.S.

[6]Except for Canada, FSIS is updating equivalency reviews sequentially by risk area. For example, analysis of the contamination risk area has been completed for all major exporting countries, and the disease risk area is being analyzed for the major exporters now.

and foreign inspection systems. Given the difficult judgments made by FSIS on scientific and public health matters, in which contrary opinions may exist, validation of these judgments and the overall equivalency process could be an important contribution to the credibility of the process.

Canada Has Been Inspecting a Larger Share of U.S. Meat Imports

Since the inception of the streamlined program, Agriculture Canada's annual inspection rate for U.S. products has been over twice that of USDA's inspection rate for Canadian products. Agriculture Canada, on average, inspected about 46 percent of all U.S. meat shipments offered for entry into Canada, compared with an average USDA inspection rate for Canadian products of about 20 percent. Much of the disparity between the two countries' rates is explained by differences between their inspection procedures under the streamlined program. For instance, because Agriculture Canada port inspectors check documentation on every U.S. shipment, they have a greater opportunity to identify deficiencies in paperwork. In fact, paperwork deficiencies is the largest single category in which Canada rejects U.S. meat products, accounting, in 1989-91, for 45, 60, and 67 percent of rejections, respectively. If a shipment is rejected because of paperwork deficiencies, the plant that produced the product must pass 10 consecutive inspections to requalify for random inspection. FSIS officials were unaware of the relatively high Canadian inspection rate until we brought it to their attention.

In contrast to the disparity in the inspection rates, rejection data lacked a pattern—the rejection rate (by weight) for U.S. meat was lower than that of Canadian meat in 1989 but was higher in 1990 and 1991. Appendix IV summarizes the two countries' inspection and rejection data from 1989 through 1991. Also, our July 1990 and October 1991 reports include detailed data on U.S. inspection and rejection of Canadian meat.[7]

Differences Under Streamlined Procedures to Be Addressed by Newly Agreed-Upon Alternative Measures

At the time of our review, the following procedures were in effect under the streamlined program for Canadian meat. FSIS' sampling methodology was based on 3,000 randomly selected inspections annually for Canada as a whole. To determine whether a planned shipment would be subject to U.S. inspection, an Agriculture Canada meat inspector would call an FSIS field office and provide information on the product to be imported. This information was entered into the FSIS computer system, which randomly selected shipments for inspection. An Agriculture Canada meat inspector would then draw the necessary samples, following FSIS instructions, and

[7]GAO/RCED-90-176 (July 6, 1990) and GAO/T-RCED-92-18 (Oct. 31, 1992).

place them in an accessible location in the rear of the truck that transported the meat. As a result, only those trucks carrying Canadian meat selected for inspection would stop for USDA reinspection, and the entire truck would not have to be unloaded. If a shipment was rejected, the plant providing the product was subject to intensified inspection for subsequent shipments. Such plants had to pass 15 consecutive inspections before they requalified for random inspection. Meat failing import inspection would be refused entry and destroyed, converted to nonhuman food use, or returned to Canada.

In contrast to FSIS' procedures and practices, Agriculture Canada port inspectors met all U.S. shipments at their Canadian port of entry, where they would examine the accompanying documentation and determine whether the shipment would be randomly assigned for inspection. In addition, these port inspectors had the option of performing a visual, tailgate inspection of the truckload. On the basis of the paperwork review and tailgate inspection, they could also have the truck unloaded (at the border) or send it on to a designated facility for full inspection by Agriculture Canada meat inspectors. In our July 1990 report, we discussed in detail U.S. and Canadian streamlined inspection procedures for imported meat.

On July 14, 1992, USDA announced that, together with Agriculture Canada, it had developed a plan to make the meat import reinspection systems more comparable. The plan addresses the controversial procedural elements that we have raised in the course of our work on this report and in previous reports by adopting the alternative measures that we identified for strengthening USDA import inspection procedures for Canadian meat. Specifically, the United States will discontinue (1) giving advance notice of inspection to Canadian plants and (2) using Agriculture Canada inspectors to draw samples. U.S. import inspectors will now select product samples. The two countries also agreed to work toward harmonizing reinspection frequency and ensuring the equivalency of other procedures.

In addition to addressing the concerns we have raised since the advent of the streamlined program, the new plan also allows imported Canadian meat to be inspected at its destination rather than at the port of entry. (All other importing countries will continue to have their products inspected at the port of entry.) Before 1986, all importers had the option of having their products inspected at the port of entry or at an inland location of their choosing (destination inspection). However, USDA's Office of Inspector General found that meat was entering U.S. commerce without inspection

because FSIS had not established adequate controls to ensure that all meat products were presented for inspection. FSIS responded by eliminating destination inspection and requiring that imported meat products from all foreign countries be inspected as soon as they enter the United States through ocean shipping ports and land ports. Allowing an exception to this policy only for those Canadian meat shipments assigned an inspection appears reasonable provided the new procedures include proper controls to ensure the integrity of the shipment before inspection.

Conclusions

In our view, to be successful, free trade in food products such as meat must be based on an assurance that the safety of U.S. food supplies will not be compromised. Equivalency determination requires scientific and public health judgments, and although FSIS will be required to complete equivalency reviews for many countries in the future, no outside, independent assessment has corroborated the validity of FSIS' process and related judgments for determining equivalency. Furthermore, U.S. exports must be treated the same as the products Canada exports to the United States. On July 14, 1992, USDA and Agriculture Canada announced a plan to replace the current streamlined procedures with alternative, equivalent procedures. We believe the new plan provides a framework for strengthening import meat reinspection while still meeting the provisions of the Free Trade Agreement. However, given the problems FSIS experienced when it allowed inspection of imported products at inland locations, we also believe that as FSIS again allows destination inspection for Canadian meat, it must ensure that its controls over such meat before inspection are adequate to preclude the recurrence of such problems.

Recommendations

We recommend that the Secretary of Agriculture

- seek a peer review of the equivalency determination process, including how best to assess foreign monitoring programs for animal drug residues, using FSIS' review of the Canadian inspection system as a test case, and
- ensure proper controls over meat imports before reinspection as FSIS implements destination inspection for Canadian meat.

Agency Comments

We discussed pertinent information in this report with responsible FSIS and Agriculture Canada officials during the course of our work and in a conference at the end of our review. We have incorporated their views

where appropriate. However, as agreed with your offices, we did not obtain written agency comments on a draft of this report.

Scope and Methodology

Our work was conducted between November 1991 and July 1992 in accordance with generally accepted government auditing standards. To evaluate FSIS' equivalency determination for Canada, we reviewed documentation supporting the agency's study of the Canadian meat inspection system and discussed the study results with officials of the FSIS International Programs office.

To analyze data on import activity, we obtained program statistics from USDA's Automated Import Information System and from Agriculture Canada. During our previous reviews, we had confirmed that the USDA system's data were generally reliable. We did not test the reliability of the Canadian data.

To learn about recent and proposed changes in the streamlined program, we interviewed officials from Agriculture Canada and the FSIS International Programs office. We also watched U.S. meat imports undergo Agriculture Canada inspection at ports of entry and at inland inspection facilities.

As arranged with your offices, unless you publicly announce its contents earlier, we plan no further distribution of this report until 30 days from the date of this letter. At that time, we will send copies to the Secretary of Agriculture; the Administrator, FSIS; and interested congressional committees. We will send copies to other interested parties upon request.

Our work was performed under the direction of John W. Harman, Director, Food and Agriculture Issues, who can be reached at (202) 275-5138. Other major contributors to this report are listed in appendix V.

J. Dexter Peach
Assistant Comptroller General

Contents

Abbreviations

FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GAO	General Accounting Office
USDA	United States Department of Agriculture

FSIS' Systems Approach for Determining Equivalency

The Federal Meat Inspection Act requires that meat imports be produced under inspection systems that are at least equal to that of the United States and that the imports be wholesome, unadulterated, and properly marked, labeled, and packaged. The United States Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) carries out these requirements through an import control program centered on (1) a review of foreign inspection systems for equivalency supplemented by on-site reviews of inspections in foreign plants[1] and (2) port-of-entry (border) reinspection of imported meat. FSIS does not require that a foreign country's controls and practices be identical to those of the United States, but they must achieve the same results.

FSIS considers the eligible foreign countries' inspection systems the primary control that imported meat products meet U.S. standards.[2] Port-of-entry inspections are intended to check the effectiveness of foreign inspection systems in ensuring that imported products are wholesome, accurately labeled, and meet U.S. standards.

FSIS reviews a foreign country's inspection system through a systems risk analysis. Developed in the early 1980s, this approach uses risk profiles that focus on five specific risk areas to be analyzed as part of a review of the country's meat inspection system as a whole. Risk-area analysis (1) assesses the severity, probability, and impact of a hazard and (2) measures each country's ability to control the hazard. Risk-area analysis is an ongoing, dynamic process that reflects changes occurring in the country's system rather than looking at the system only once.

As part of the risk-area analyses, USDA developed risk profile instruments for each of the five risk areas: contamination, disease, economic fraud/compliance, processing, and residues. Each instrument addresses a number of critical review points; there are 50 critical review points in all (see app. II). For each critical review point, the instrument lists information to be obtained. (The profiles generally begin by requesting a "yes" or "no" response on whether the country's inspection system includes that point.) The instrument also provides guidance to assist the reviewer in determining if deviations from the U.S. standards on the point

[1]FSIS has a staff of foreign program officers who are licensed veterinarians with experience in domestic inspection. These officers evaluate foreign inspection systems and conduct periodic reviews of establishments certified to export meat products to the United States to determine if U.S. requirements are being met.

[2]U.S. inspection standards required of other countries include the use of (1) competent, qualified inspectors and (2) national inspection officials with sufficient authority and responsibility to enforce meat inspection laws and regulations and to certify or refuse to certify products intended for export.

are critical, major, or minor. Where applicable, the profile instrument requests information on the country's statutory authority for the standards or practices it follows on each point. Within each risk area, the information to be obtained is divided into the following categories: standards, activities, resources, enforcement, and (only in the residue profile) evaluation.

For example, the first critical review point in the contamination risk profile is "structure/facilities design controls." The standards section asks whether the country's inspection system has design guidelines for plants and facilities; adequate identification of export plants; and design guidelines for water supply, sewage disposal, and plant construction. The activities section asks whether the country (1) has the authority to deny export certification to a plant that does not meet structure/facilities design standards, (2) requires plant design approval, and (3) requires blueprints to be updated as needed. The resources section asks about the availability of personnel to conduct certain functions. The enforcement section questions whether the country withdraws operating approval for plants that do not meet design standards and also questions how inspectors enforce construction standards and control approval of blueprint and design changes.

FSIS' risk analysis of the Canadian system was based on both completion of the risk profiles and on-site evaluations of the Canadian inspection system. To complete the risk profiles, FSIS first obtained Canadian responses to questionnaires (covering the five risk areas), then supplemented this information with source materials such as laws, regulations, and guidance material governing Canada's inspection system. FSIS next sent a multidisciplinary team on site to evaluate all aspects of Canada's inspection system in operation, including its laboratories and individual plants (30 visits), and to conduct interviews with Canadian officials. FSIS reported the results of the review in March 1992.[3]

[3]Equivalency Study of the United States and Canadian Meat and Poultry Inspection Systems: Summary Report (International Programs, Food Safety and Inspection Service, Mar. 1992).

Critical Review Points for Risk-Area Analysis

Contamination (13 critical review points)

- structure/facilities design controls
- equipment design controls
- water quality controls
- slaughter and dressing controls
- boning and fabrication controls
- operations sanitation controls
- product segregation controls
- employee health, dress, and cleanliness controls
- maintenance controls
- nonfood-item controls
- pest controls
- temperature controls
- transportation controls

Disease (4 critical review points)

- animal husbandry practices
- documentation of endemic diseases
- foreign disease control practices
- slaughter inspection controls

Compliance/Economic Fraud (6 critical review points)

- certified plant controls/inspector integrity
- inspection devices
- deceptive packaging and labeling
- product identification and control
- species verification
- transportation/storage controls

Processing (12 critical review points)

- ingredient (additives) acceptance
- ingredient/food additive handling
- packaging material approval
- container integrity
- ingredient preparation
- formulation procedures
- processing specifications
- process operating procedures

- operating effectiveness
- label and code application
- product compliance-to-label statement
- storage temperature

Residues (15 critical review points)

- drug approval and licensing controls
- user controls (animal drugs)
- feed controls (animal drugs)
- compound approval and licensing controls
- user controls (pesticides)
- feed controls (pesticides)
- knowledge of environmental contamination sources
- source-country evaluation
- product entry controls
- knowledge of livestock production system
- laboratory evaluation
- metabolism studies
- laboratory quality
- sampling program design analysis
- violation follow-up

Certain Differences Between the U.S. and Canadian Meat Inspection Systems

This appendix discusses three areas of differences between the U.S. and Canadian meat inspection systems. These differences occur in the detection and control of the bacteria Listeria monocytogenes (hereinafter referred to as listeria); the approval, use, and monitoring of animal drugs; and the lists of foreign countries approved to export meat products. The congressional requesters of this assignment specifically asked for additional information on the last two issues.

Listeria Detection and Control

Of the various sources of food contamination, microbes probably pose the greatest risk to human health. Harmful microbes in food cause nearly all cases of acute food-borne illness in the United States each year. Because many cases go undiagnosed, the actual figure is probably much higher than the conservative figure of 6.5 million annually and may be at least 24 million, according to an estimate by Food and Drug Administration (FDA) officials.

Apart from salmonella, which is well known to the public, scientists have lately identified other harmful organisms, including listeria, as serious threats. The first recognized outbreak of food-borne illness due to listeria infections in the United States occurred in 1983 and was associated with consumption of one brand of pasteurized milk. Listeriosis, although less common than other food-borne diseases such as salmonellosis, has a high mortality rate. Each year, listeriosis strikes about 1,850 Americans; nearly one-fourth of those people die. Microbiologic surveys have documented that listeria may be present in a wide range of retail foods, including processed, ready-to-eat meat products such as lunch meats and frankfurters.

U.S. federal agencies gave higher priority to listeria control following the January 1989 death of an elderly patient who had consumed tainted meat. Consequently, the United States and Canada have discussed differences in their policies on listeria. One difference we identified in the two countries' policies is that the U.S. program tests end products to detect the presence of the bacteria while the Canadian program relies on environment testing (of workers and work areas) for initial detection but uses end-product testing to check and control an identified problem.

At first, FSIS considered Canada's environmental sampling focus unacceptable. In a July 13, 1990, letter to Agriculture Canada, the FSIS Administrator stated: "Canada does not have a listeria program equivalent to that of the United States (U.S.) because Canada samples the

environment whilst the U.S., samples the ready-to-eat food." Agriculture Canada did not agree—while it concurred that the respective program approaches might differ in some respects, it also believed that the Canadian program's objectives and final results were of the same nature. When over the next several months USDA and Agriculture Canada were unable to settle the issue, they decided to resolve it during the equivalency review process.

When we pursued this issue, both FSIS and Agriculture Canada officials told us that, though not addressed in the summary report, the difference does not indicate a lack of equivalency. Officials from both countries no longer had any serious concerns about the other country's listeria detection and control procedures even though the procedures were not identical. Nevertheless, officials from both countries also said that they recognize that the differences in their procedures for listeria detection and control continue to perpetuate debate and criticism over whether or not a "best" method for detection and control exists, and what that method might be. Thus, harmonization in methods of listeria control and monitoring will continue to be a subject of ongoing discussion.

Animal Drug Use and Monitoring

Unsafe levels of animal drug residues in food can result in potentially dangerous health consequences for consumers. Such residues have been linked to allergic reactions and some types of cancer. In addition, some scientists are concerned about the potential problem of the increased incidence of drug-resistant bacteria that have evolved as a result of the use of animal drugs. Because of these concerns, most animal drugs must be approved by FDA before they can be legally marketed in the United States.

FDA is responsible for ensuring that animal drugs are safe and effective for their intended use and do not result in unsafe residues in foods from treated animals. When approving the use of an animal drug, FDA establishes the related acceptable level of residues. FDA also establishes the approved methods of use for specific animals (for example, the minimum length of time before slaughter that a particular drug may not be administered, called a withdrawal period) to ensure that the acceptable residue levels will not be exceeded. FSIS uses animal drug requirements set by FDA in the guidance it provides to foreign countries exporting meat product to the United States. FSIS also monitors animal drug residues in imported products as part of its overall import inspection program. However, other countries have their own animal drug approval and regulatory systems, that may differ in certain respects from the U.S.

system. For example, because of climate conditions or public health concerns unique to its region, a foreign country may approve drugs not approved in the United States or establish different acceptable levels of residues.

In reviewing FSIS' equivalency review documentation on the residue risk of animal drugs, we looked for evidence of any differences between the United States and Canada in their approval of animal drugs for use on food-producing animals. We found that the scope of the equivalency review did not include identifying drugs approved and used in Canada but not in the United States. In explaining this discrepancy, FSIS officials told us that, consistent with the systems approach to risk analysis, the equivalency review in the area of residue risk focused on making sure that Canada had a reasonable system for animal drug approval and residue monitoring. In their view, the equivalency documentation shows that Agriculture Canada has such a system for animal drug approval, licensing, and residue monitoring.

Foreign countries that export meat to the United States, including Canada, must receive an annual certification from the Secretary of Agriculture that they maintain a program to ensure compliance with U.S. standards for residues in meat products. USDA also mandates that all meat-exporting countries monitor for chloramphenicol, diethylstilbestrol, specified antibiotics, chlorinated hydrocarbons, organophosphates, polychlorinated biphenyls, sulfonamides, and trace elements (mostly heavy metals such as arsenic, cadmium, lead, and mercury). FSIS officials told us that beyond the mandated testing, it is up to Agriculture Canada to implement control programs to ensure that residues of animal drugs in meat exports to the United States do not exceed U.S. standards. FSIS annually receives the results of Canada's residue monitoring activity from the previous year and the plan for the next year.

Nevertheless, under the Federal Meat Inspection Act, FSIS is responsible for ensuring that meat products from Canada (like those from all other countries exporting meat into the United States) comply with inspection standards, including residue standards, at least equal to those of the United States. Therefore, specific knowledge of all differences in drug approvals is important to determine the thoroughness of the Canadian domestic meat residue monitoring program as well as the adequacy of the U.S. program for monitoring imported Canadian meat. Knowledge of drug approval differences could alert FSIS to the need for (1) Canada to monitor

for some drug residues domestically and (2) the United States to monitor imported Canadian meat products.

Previous reports by GAO and USDA's Office of Inspector General have raised concerns about the lack of information in this area for all countries exporting to the United States. A 1989 USDA Office of Inspector General report pointed out that four foreign countries (including Canada) received the required certification of residue compliance from USDA even though they allowed the use of animal drugs not approved in the United States, but did not include these drugs as part of the residue test plans.[1] (Of the four countries, Canada had the fewest number of drugs not approved in the United States.) The report recommended that FSIS ensure that foreign countries' residue test plans include drugs that are not approved or have not been presented for approval for use in the United States. Furthermore, the report recommended that the plans should provide a rationale for including or excluding any such drugs from residue testing.

Although FSIS responded positively to the recommendation, it has not comprehensively acted upon it in regard to Canada. In a March 1989 letter, the FSIS Administrator advised the Inspector General that FSIS had already begun documenting and evaluating drug use in countries certified to export meat products to the United States. The Administrator explained, however, that such analysis was not simple or clear-cut and estimated that the project, which began in July 1987, would take 5 years to complete. When we evaluated the equivalency review documentation on Canada, FSIS did not have complete information on Canadian animal drugs that are either not approved or have not been presented for approval in the United States. In fact, the most current FSIS listing of animal drugs used in Canada was 4 years old.

While our attempt to identify drugs approved for use on food- producing animals in Canada but not in the United States was not comprehensive, we did find that dimetridazole, dinsed,[2] furazolidone,[3] nifursol, nitrofurazone, rolitetracycline, and ronidazole met this description. These drugs represent varying degrees of potential risk to human health and safety, on the basis of Agriculture Canada's risk ranking system for chemical compounds. Although Canada's 1992 residue testing plan shows coverage

[1]Food Safety and Inspection Service Follow-up Audit of the Imported Meat Process (Audit Report No. 38002-4-Hy, Mar. 29, 1989).

[2]Abbreviated form of dinitrodiphenylsulfonylethylenediamine.

[3]Although furazolidone is no longer approved for internal use in food-producing animals in the United States, it is still approved for ophthalmic use on cattle.

of the first six of the seven drugs listed, the drugs present a potential problem. Under the Federal Meat Inspection Act, meat and meat products containing residues of drugs not approved for use on food-producing animals in the United States cannot be imported.

However, FSIS has taken action when some of these drugs have come to its attention. For example, FSIS requested that Agriculture Canada increase its monitoring for dimetridazole, a possible carcinogen. Also, after FDA's September 1991 withdrawal of approval for two other possible carcinogens (furazolidone and nitrofurazone), USDA requested that Agriculture Canada reinstate a testing program for nitrofurans. Still, despite these actions, USDA has not systematically identified animal drugs approved in Canada but not in the United States. Without this identification, FSIS lacks an important basis for determining the possible risk from animal drug residues in Canadian meat products.

In addition to lacking information on animal drugs approved in Canada, we found a related weakness in U.S. residue testing of Canadian meat imports. While U.S. residue testing is not meant to substitute for or supplement Canadian testing, it is intended to be a spot-check of Canada's monitoring program. However, the U.S. import residue testing program is not based on independent judgments about the risk of particular drug residues in the meat products from foreign countries. Instead, USDA sets up its laboratories to analyze drugs it considers important to test for in domestic meat. Import program residue testing mirrors, though on a smaller scale, the priorities of the domestic analysis program. However, this testing may not address drug usage in foreign countries, including Canada.

Certification of Other Foreign Countries

Because imported meat from a third country may be used in the preparation of products exported to the United States, USDA requires that countries exporting meat to the United States have controls to ensure compliance with U.S. residue regulations and standards on meat they acquire from foreign sources. USDA also requires that exporting countries control the entry of meat products from countries where diseases are present that do not occur within their territory. FSIS' equivalency review of Canada reported that, like the United States, Canada has a certification program to ensure that a foreign country's inspection system complies with certain requirements before that country can export meat to Canada. Neither country will accept meat products from a country it has not certified as eligible to export the products.

Comparing countries certified to export meat to the United States and Canada, we identified 3 countries that are eligible to export meat to Canada but not to the United States and 13 that are eligible to export meat to the United States but not to Canada. We reviewed the reasons for these differences to ascertain whether the differences could affect FSIS' determination that the Canadian inspection system is equivalent to the U.S. inspection system.

We found that the differences in which foreign countries are eligible to export meat products to the United States and Canada do not reflect any differences between the two countries' process for certifying foreign countries as eligible to export meat products. In none of the cases we found was the foreign country certified by one country denied eligibility by the other country because of public health or safety concerns. Instead, the differences in eligible foreign countries generally reflect differences in the trading preferences of the foreign countries. That is, foreign countries do not always desire to export to both countries and, therefore, only request certification in one or the other country. Also, the amount of time each country takes to approve a foreign country's certification (including site visits, completion of paperwork, and granting of final approval) can vary. The one exception is Nicaragua, which reflects a special situation.

Until recently, Nicaragua was eligible to export to Canada but not to the United States. Nicaragua exported beef products to the United States as recently as 1985. In 1986, FSIS removed Nicaragua from the list of countries eligible to export meat to the United States. FSIS took this action after its representatives were unable to review the Nicaraguan meat inspection system in order to obtain the current information necessary to maintain the country's eligibility because their personal safety could not be assured. More recently, a final rule re-establishing Nicaragua's eligibility to export to the United States was published in the July 10, 1992, Federal Register. Accordingly, Nicaragua became eligible to export cattle, sheep, swine, and goat products to the United States as of August 10, 1992.

Both FSIS and Agriculture Canada officials said that the possibility of meat products from an ineligible foreign country entering their countries through the other country does not present a problem. They offered similar explanations: A country that is eligible to export meat products to, for example, the United States, but not eligible to export to Canada, could ship meat products to the United States, where the products could be combined with U.S. products in further processing, re-packaged and marketed by a U.S. company. In this case, the product assumes a U.S.

identity and becomes subject to all USDA standards and requirements. As such, these officials explained, Agriculture Canada would have no problem accepting the product under the same terms as any other product from the United States. If the same product were shipped through the United States to Canada without assuming a U.S. identity through U.S. processing and packaging, the product would not have USDA quality assurances and would be rejected at the Canadian border because it came from an ineligible country of origin.

U.S. and Canadian Meat Exports, 1989-91

The following tables and figures provide additional information on the amounts of meat offered, inspected, and rejected in trade between the United States and Canada from 1989 through 1991. Table IV.1 and figure IV.1 both measure this information measured in product lots. Table IV.2 and figure IV.2 show the information in pounds. The figures seem to provide contradictory information because they show that the United States exports fewer pounds but more lots than Canada. However, the lot weight of U.S. products average less than half those of Canadian products. Over the 3 years, U.S. lots averaged 11,283 pounds compared with 26,270 pounds for Canadian lots.

Table IV.1: Lots of U.S. and Canadian Meat Exports Offered, Inspected, and Rejected

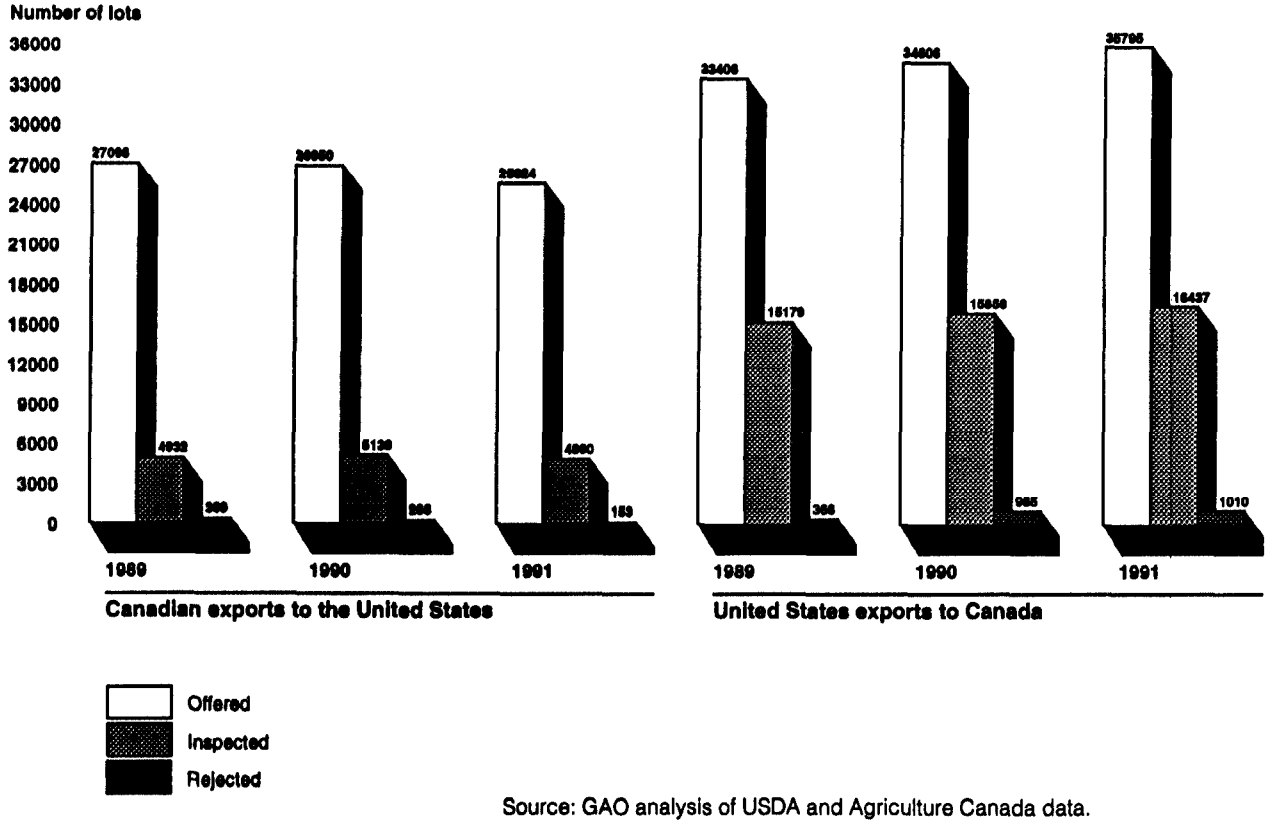
	1989		1990		1991	
Canadian exports to the United States	**Lots**	**Percent**	**Lots**	**Percent**	**Lots**	**Percent**
Offered	27,098		26,950		25,624	
Inspected[a]	4,932	18.2	5,319	19.7	4,860	19.0
Rejected[b]	369	7.5	288	5.4	153	3.1
United States exports to Canada						
Offered	33,406		34,606		35,795	
Inspected[a]	15,179	45.4	15,858	45.8	16,437	45.9
Rejected[b]	368	2.4	985	6.2	1,010	6.1

[a]Lots inspected include random and intensified inspections combined. We used a combined total because, while USDA was able to provide a breakdown, Agriculture Canada did not have separate data for the two kinds of inspections.

[b]Lots are rejected for both product examination failures and other reasons. Other reasons include labeling defects, missing shipping marks, violative net weight, transportation damage, and inadequate documentation.

Source: GAO analysis of USDA and Agriculture Canada data.

Figure IV.1: Comparison of Lots of U.S. and Canadian Meat Exports Offered, Inspected, and Rejected



Source: GAO analysis of USDA and Agriculture Canada data.

Table IV.2: Pounds of U.S. and Canadian Meat Exports Offered, Inspected, and Rejected

Pounds in Millions

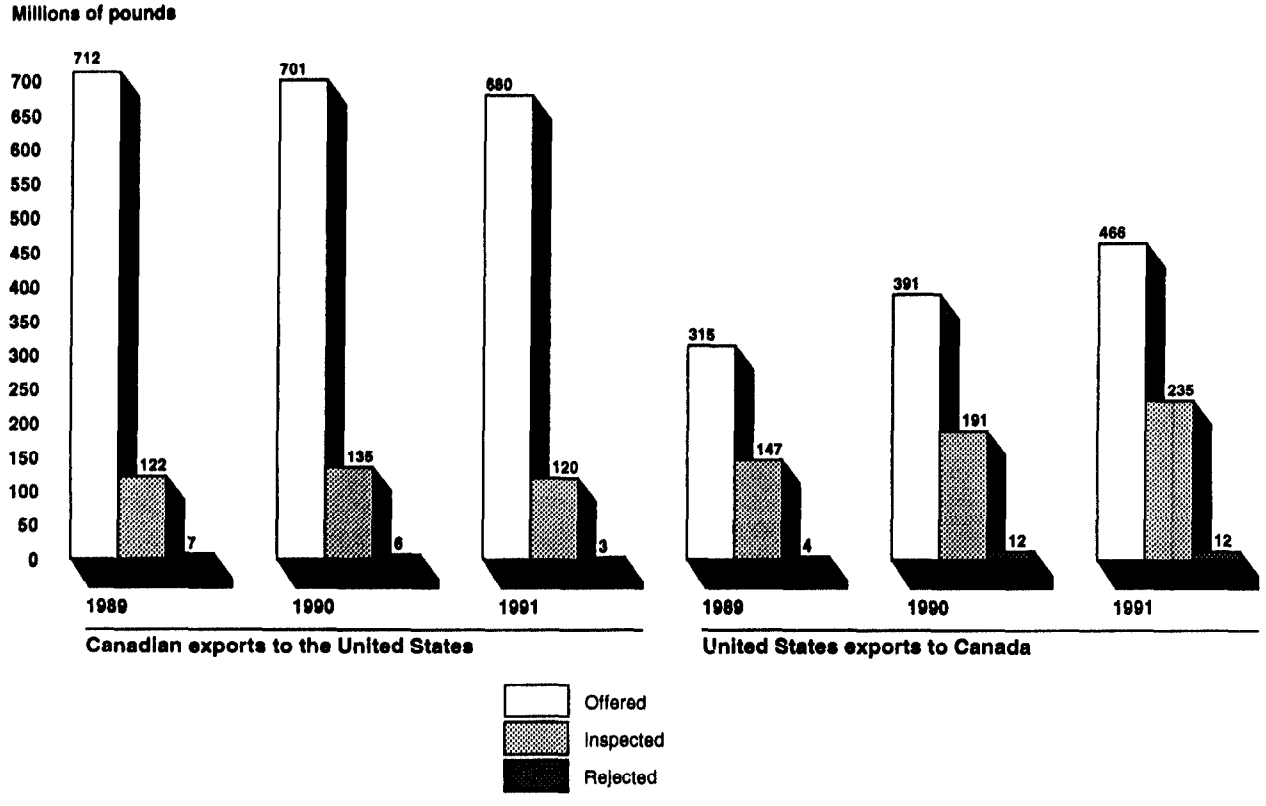
	1989		1990		1991	
Canadian exports to the United States	**Pounds**	**Percent**	**Pounds**	**Percent**	**Pounds**	**Percent**
Offered	711.69		701.21		680.09	
Inspected[a]	121.69	17.1	135.24	19.3	119.83	17.6
Rejected[b]	7.18	5.9	6.38	4.7	3.16	2.6
United States exports to Canada						
Offered	314.94		390.68		465.64	
Inspected[a]	147.01	46.7	190.51	48.8	234.66	50.4
Rejected[b]	4.46	3.0	12.34	6.5	12.39	5.3

[a]Pounds inspected include random and intensified inspections combined. We used a combined total because, while USDA was able to provide a breakdown, Agriculture Canada did not have separate data for the two kinds of inspections.

[b]Pounds are rejected for both product examination failures and other reasons. Other reasons include labeling defects, missing shipping marks, violative net weight, transportation damage, and inadequate documentation.

Source: GAO analysis of USDA and Agriculture Canada data.

Figure IV.2: Comparison of Pounds of U.S. and Canadian Meat Exports Offered, Inspected, and Rejected



Source: GAO analysis of USDA and Agriculture Canada data.

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